

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION OPIATE
LITIGATION

This document relates to:

*Broward County, Florida v. Purdue Pharma
L.P.*, No. 18-op-45332

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**REPLY IN SUPPORT OF THE MANUFACTURER DEFENDANTS'
JOINT MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT**

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INTRODUCTION

The County's Brief in Opposition ("Opp.") fails to cure the deficiencies identified in the Manufacturer Defendants' Joint Motion to Dismiss ("JM"), so the Court should dismiss the Second Amended Complaint ("2AC") in its entirety.¹ Further, because the majority of the County's responses mirror those in *Summit*, the Manufacturer Defendants expressly incorporate by reference their reply brief in the *Summit* action, Dkt. No. 764 ("*Summit* Reply"). This brief addresses only issues unique to the *Broward* action.

ARGUMENT

I. THE COUNTY LACKS STANDING

The County does not dispute that it is merely a "political subdivision[] of the state," Opp. 10, and that, under Florida law, "matters of general and statewide significance, are not proper subjects for local treatment." *City of Miami Beach v. Fleetwood Hotel, Inc.*, 261 So. 2d 801, 804 (Fla. 1972). This alone requires dismissal of the County's claims for lack of standing. The County argues that the statewide concern doctrine is limited to legislation, as opposed to litigation. Opp. 11-12. But the Supreme Court of Florida has made clear that political subdivisions "are established for purposes of *local* government, and, in the absence of specific delegation of power, *cannot engage in any undertakings* not directed immediately to the accomplishment of those purposes." *Fleetwood Hotel*, 261 So. 2d at 803. This limitation clearly precludes bringing duplicative litigation over a statewide issue that the Florida Attorney General has already exercised its power to sue over. JM 2-3. Although the powers afforded to counties in Florida may be broad, *see* Opp. 10, "[l]ocal governments have not

¹ Unless otherwise noted, all capitalized terms and acronyms are defined in the Memorandum in Support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiff's Second Amended Complaint (Dkt. #593-1) ("Motion" or "JM"), emphasis in quotations is added, and internal citations, quotation marks and alterations are omitted. "Opposition" or "Opp." refers to Plaintiff's Omnibus Memorandum in Opposition (Dkt. #730).

been given omnipotence by home rule provisions or . . . the 1968 Florida Constitution.” *Fleetwood Hotel*, 261 So. 2d at 804.

II. THE FEDERAL AND STATE RICO CLAIMS FAIL (COUNTS 1-4)

The federal RICO claims fail for the reasons stated in *Summit*. As the County itself concedes, “[i]nterpretation of Florida RICO is informed by case law interpreting the federal RICO statute.” Opp. 56-57; *see also Jackson v. BellSouth Telecomms.*, 372 F.3d 1250, 1263 (11th Cir. 2004); *Ruth v. State Dep’t of Legal Affairs*, 661 So.2d 901, 904 (Fla. Dist. Ct. App. 1995). The County’s failure to plead any federal RICO violation thus compels dismissal of its Florida RICO claims as well. *See* JM 4-5; *see also Summit* JM §§ II-III.

III. FEDERAL LAW PREEMPTS THE COUNTY’S STATE LAW CLAIMS

The County relies on the preemption arguments set forth in *Summit*. Opp. 9. The County therefore concedes it is not pursuing many claims, *Summit* Reply 11, and, as the Manufacturer Defendants have explained, any remaining claims cannot escape preemption. *Id.* 11-13.

IV. THE COUNTY’S PUBLIC NUISANCE CLAIM FAILS (COUNT 6)

A. Florida Recognizes a Safe Harbor, Which the County Cannot Circumvent

The County’s assertion that Florida public nuisance law recognizes no “safe harbor,” Opp. 18, is incorrect. Florida’s public nuisance doctrine “does not apply to the design, manufacture, and distribution of a lawful product” and it cannot be used by a county to “regulate . . . through the medium of the judiciary” where the County’s regulatory authority is preempted. *Penelas v. Arms Tech., Inc.* 1999 WL 1204353, at *4 (Fla. Cir. Ct. 1999), *aff’d*, 778 So. 2d 1042 (Fla. Dist. Ct. App. 2001). The County then attempts to avoid the very safe harbor it asserts does not exist by purporting to limit its claim to one based only on allegedly “illegal and fraudulent acts, already in violation of numerous regulations, which interfered with a public right.” Opp. 19. But the County’s allegations still misunderstand the Manufacturer Defendants’ regulatory obligations, lack sufficient particularity, and

implicate individual rights, as discussed in *Summit*. *Summit* Reply 27-28 & n.23. Further, the authorities on which the County relies either are Florida decisions addressing conduct that, unlike here, has been expressly declared by statute to be a public nuisance,² or else are unavailing for the reasons discussed in *Summit*. *Summit* Reply 27 n.23.

B. The County Cannot Plead Actual or Proximate Causation

Penelas makes clear that under Florida law, “a party cannot be held liable for nuisance absent control of the activity which creates the nuisance.” 1999 WL 1204353 at *4. The County now claims that *Penelas* is distinguishable because the Manufacturer Defendants allegedly engaged in fraud and the third parties who engaged in independent, intervening acts and criminal conduct were not “unforeseen actors.” Opp. 18, 20. But, just as the County alleges here, *Penelas* similarly involved allegations of wrongful conduct and generalized awareness by defendants of unlawful actors in secondary criminal markets. 778 So.2d at 1044. And, just as in *Penelas*, the County’s conclusory allegations here are insufficient to establish the Manufacturer Defendants’ required control over third parties, particularly given the lawful uses for their prescription opioid products. *Id.* Nor does the County account for the independent decision-making of prescribers in its flawed causal chain.

C. The Municipal Cost Recovery Rule Bars The Public Nuisance Claim

Lastly, the County urges the Court to ignore *Penelas*’s holding that “expenditures made in [the County’s] performance of governmental functions” are “not, without express legislative authorization, recoverable by governmental entities.” 1999 WL 1204353 at *2; Opp. 14. But the County identifies no Florida case overruling or disapproving of *Penelas*, and, in any event, offers no persuasive rationale

² *Orlando Sports Stadium, Inc. v. Florida*, 262 So. 2d 881, 884 (Fla. 1972); *Estep v. State*, 23 So. 2d 482, 483 (Fla. 1945); *Prior v. White*, 180 So. 347, 355 (Fla. 1938).

as to why *Penelas*'s ruling is incorrect. The Florida municipal cost recovery rule thus bars the County's public nuisance claim.

V. THE COUNTY'S NEGLIGENCE CLAIMS FAIL (COUNTS 7-9)

The Opposition fails to address the numerous deficiencies in the County's negligence claim. First, the County claims that the Manufacturer Defendants owed a duty because of their "special relationship as manufacturers . . . of pharmaceutical opioids purchased by Broward." Opp. 22. However, Florida law recognizes no such special relationship. JM 8. Further, the County contends a duty of care arises "when one actor simply has superior knowledge to the other." Opp. 26. But Florida has squarely rejected such a rule. *Aguila v. Hilton, Inc.*, 878 So. 2d 392, 397 (Fla. Dist. Ct. App. 2004). Plaintiff relies upon *Shurben v. Dollar Rent-A-Car*, 676 So. 2d 467 (Fla. Dist. Ct. App. 1996), but in that case the defendant utterly failed to give *any* warnings to its *own customer*, whereas here it is undisputed that Manufacturer Defendants, through FDA-approved labeling, fully warned physicians of the risk of opioid medications. *See Knight v. Merhige*, 133 So. 3d 1140, 1149 (Fla. Dist. Ct. App. 2014) (duty to warn in *Shurben* "arose out of a business relationship"); *Felix v. Hoffmann-LaRoche, Inc.*, 540 So.2d 102, 105 (Fla. 1989) (drug maker has duty to warn only physicians).

Nor can the County save its negligence claims by relying on two inapplicable cases. Opp. 26-27. One is an out-of-state case that does not analyze Florida law. *Everett v. Purdue Pharma L.P.*, 2017 WL 4236062 (W.D. Wash. 2017) (analyzing Washington law). The other involved the anomalous and distinguishable duty of a government lab to protect "ultrahazardous" anthrax under its control. *United States v. Stevens*, 994 So. 2d 1062, 1070 (Fla. 2008). Indeed, at least one Florida court has already rejected the expansion of *Stevens* beyond its unique facts. *See Cook v. MillerCoors, LLC*, 829 F. Supp. 2d 1208, 1217 (M.D. Fla. 2011).

Lastly, the County asserts that its negligence *per se* theory does not impermissibly seek to enforce "statutory duties." Opp. 27-30. But Florida will not recognize a claim for negligence *per se*

based on a violation of a statute unless the underlying statute itself provides a private right of action. *Owens-Benniefield v. Nationstar Mortg. LLC*, 258 F. Supp. 3d 1300, 1316 (M.D. Fla. 2017). The CSA and its purported companion Florida statutes, Opp. 28, do not provide a private right of action. JM 8.

VI. THE COUNTY'S FRAUD CLAIM (COUNT 11) FAILS

The County's fraud claim should be dismissed because the County has not alleged *its own* detrimental reliance on any purported misrepresentation by any of the Manufacturer Defendants. *See* JM 9-10; *Rand v. Nat'l Fin. Ins. Co.*, 304 F.3d 1049, 1052 (11th Cir. 2002) (fraud requires actual detrimental reliance). The County's bare-bones allegations of reliance, 2AC ¶¶ 808, 912, are entirely conclusory and deficient, and certainly fall far short of the particularity required under Rule 9(b). *Evans v. Pearson Enterprises*, 434 F.3d 839, 852-53 (6th Cir. 2006) ("Conclusory statements of reliance are not sufficient to explain with particularity how [a plaintiff] detrimentally relied on the alleged fraud.").

VII. THE FDUTPA CLAIM FAILS (COUNT 5)

A. The FDUTPA Claim Is Barred by the Safe-Harbor Provision

FDUTPA liability cannot be based on promotion consistent with FDA-approved product labeling. *See* JM 10. Despite not contesting this principle, the County nevertheless maintains that the safe harbor is inapplicable to claims premised on the nine categories of misrepresentations alleged at 2AC ¶ 146. Opp. 51. But each of these categories includes alleged misrepresentations that relate either to the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain (*e.g.*, 2AC ¶ 146 (a)-(c), (f)-(i)) or to the dosage and FDA-approved use of the medications (*e.g.*, *id.* (d)-(e)). Therefore, the County's FDUTPA claim based on the advertising and promotion of extended-release opioids fails. *See* JM 10.³

³ The County does not cite any authority to rebut the cases cited in the Motion. Instead, the County claims that *Prohias* "actually supports Broward" because "[t]he court rejected the safe harbor defense at the pleading stage." Opp. 51 n. 32. But there, the Court held that plaintiffs' false advertising claims *after FDA's approval* of the medication for the indication related to the

B. The County Does Not Allege It Was Involved In A Consumer Transaction

The FDUTPA claim also fails because (1) the County did not incur expenditures as a “consumer” of the Manufacturer Defendants’ opioids, and (2) the County does not qualify as a “consumer” for FDUTPA purposes simply by virtue of its alleged purchase or reimbursement of opioids for business reasons. JM 11. Despite these pleading deficiencies, the County instead cherry-picks cases applying the FDUTPA broadly, and insists that the FDUTPA is not limited to consumer transactions. Opp. 43. This argument, however, ignores that “the overwhelming weight of authority [is] in favor of a narrow reading . . . [that] FDUTPA applies only to a consumer injured by an unfair or deceptive act when buying or purchasing goods and services.” *Taft v. The Dade Cty. Bar Ass’n, Inc.*, 2015 WL 5771811, at *4 (S.D. Fla. 2015); *Gibson v. Resort at Paradise Lakes, LLC*, 2017 WL 3421532, at *5 (M.D. Fla. 2017). The Court should adopt these authorities and dismiss the County’s FDUTPA claim accordingly.

C. The County Fails to Plead the Elements of a FDUTPA Claim

The Opposition fails to identify any false or misleading statements by any Manufacturer Defendant connected to any specific prescription, doctor, patient, or alleged harm in the County. JM 12; Opp. 45-48. Nor does the Opposition address the uniform authorities cited in the Motion establishing that allegations of off-label promotion are not actionable because “courts and the FDA have recognized the propriety and potential public value of unapproved or off-label drug use,” and because “the promotion of off-label drug use is *not in and of itself false or misleading*.” JM 12 n.8 (quoting *United States v. Caronia*, 703 F.3d 149, 165 (2d Cir. 2012)).

advertisement at issue were “barred by the applicable state safe harbor statutes.” *Prohios v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1234 (S.D. Fla. 2007). That rule bars the County’s claims here.

Instead, the County argues only that it has pleaded a *per se* FDUTPA violation by establishing violation of the FDCA and CSA. Opp. 47. But those allegations are directed only to the Distributor Defendants, not the Manufacturer Defendants. *See* 2AC ¶ 926. Moreover, there is no *per se* violation of FDUTPA unless the underlying statute “proscribes deceptive or unfair practices.” Opp. 46. The Opposition, however, cites no authority establishing that the CSA meets that definition. *Id.* 47. Nor can the County usurp the exclusive enforcement authority of the DEA and FDA by using FDUTPA to circumvent the absence of a private cause of action under either the FDCA or CSA. *Buell v. Direct Gen. Ins. Agency, Inc.*, 267 F. App’x 907, 909 (11th Cir. 2008).

The County also has not pleaded any “actual damages” within the meaning of FDUTPA, let alone identified any harmful prescriptions caused by the Manufacturer Defendants’ alleged fraud. JM 12-13. Indeed, the County implicitly concedes that FDUTPA bars recovery for downstream, consequential damages of the kind the County seeks here. *See* Opp. 49. The County further admits that the “market-value approach” to proving damages is “often required in FDUTPA cases,” Opp. 50, yet concedes that it has failed to allege a “difference in the market value of the product or service in the condition in which it was delivered and its market value in the condition in which it should have been delivered.” JM 13 (quoting *ADT LLC v. Vivint, Inc.*, 2017 WL 5640725, at *5 (S.D. Fla. 2017)). The County’s FDUTPA claim should be dismissed accordingly.

VIII. THE UNJUST ENRICHMENT CLAIM FAILS (COUNT 10)

Although the County concedes it must allege a direct benefit conferred on the Manufacturer Defendants to establish a claim for unjust enrichment, the Opposition nowhere identifies any non-conclusory allegations in the 2AC establishing such a benefit. *See* Opp. 37-40; 2AC ¶¶ 964-69. The Court should similarly reject the County’s unsupported assurance that it could “easily” cure these pleading deficiencies in the 2AC via a *third* amended complaint, as the County cannot identify any direct economic relationship between it and any of the Manufacturer Defendants here. *See* Opp. 40.

IX. THE COUNTY'S CIVIL CONSPIRACY CLAIM FAILS (COUNT 12)

The County concedes that “Florida law does not recognize a wholly independent action for conspiracy.” Opp. 60-61 (citing *Allocco v. City of Coral Gables*, 221 F. Supp. 2d 1317, 1361 (S.D. Fla. 2002), *aff’d*, 88 F. App’x 380 (11th Cir. 2003)). Because all of the County’s underlying claims are defective, the County’s civil conspiracy count fails too. *Allocco*, 221 F. Supp. 2d at 1361.⁴

X. THE COUNTY'S “CLAIM” FOR PUNITIVE DAMAGES FAILS (COUNT 13)

The County concedes that pleading punitive damages as a separate count, as the County has done here, is inappropriate, yet it urges the Court to instead excuse that error and “treat the request for punitive damages as a remedy.” Opp. 62 (citing *Flying Fish Bikes, Inc. v. Giant Bicycle, Inc.*, 2015 WL 3452517 (M.D. Fla. 2015)). But *Flying Fish* itself confirms that this Count should be dismissed, as punitive damages “must be asserted in conjunction with a substantive claim.” 2015 WL 3452517 at *3. The County has not done so, and cannot amend its complaint through its brief.⁵

XI. ALL CLAIMS ARE TIME-BARRED IN PART.

The Court should dismiss the County’s claims, in part, as time-barred because the 2AC “shows on its face that the limitation period has run,” *Edward J. Goodman Life Income Tr. v. Jabil Circuit, Inc.*, 560 F. Supp. 2d 1221, 1229 (M.D. Fla. 2008); according to the 2AC, the County was on notice of its claims before 2013. *See* 2AC ¶¶ 179, 181, 190, 198, 205, 207, 215, 217, 226, 229, 232, 239, 241-42, 254, 266, 344, 372, 404. Further, the County has not identified any action by the Manufacturer Defendants—apart from the alleged underlying fraud itself—that prevented the County from filing a timely lawsuit. *See id.* ¶¶ 697-707. Instead, the County merely stands on bare allegations that it was unaware of the facts underlying its claims. Opp. 3-9; 2AC ¶¶ 697-707. Apart from being contradicted

⁴ The conspiracy claim also fails on its own terms as discussed in the Motion. *See* JM 14-15.

⁵ Nor has the County pled any substantive claims supporting punitive damages, much less with the necessary particularity.

by other allegations in the 2AC itself, these conclusory allegations are not sufficient to plead fraudulent concealment or equitable tolling. *Heuer v. Nissan N. Am., Inc.*, 2017 WL 3475063, at *4 (S.D. Fla. Aug. 11, 2017).

The continuing violation doctrine also does not apply here because the County has pleaded only “continual harmful effects from an original, completed act.” *Suarez v. City of Tampa*, 987 So.2d 681, 686 (Fla. Dist. Ct. App. 2008). Conceding that the 2AC alleges only “discrete acts” by the Manufacturer Defendants, the County instead argues that these are “representative examples” of continuing conduct. Opp. 8. But the County cites no authority holding that a plaintiff may avoid the statute of limitations merely by pleading that independent, discrete acts are “examples” of continuous conduct. *Id.* The County’s flawed logic would negate the entire rationale behind this narrow doctrine.

CONCLUSION

For the foregoing reasons, the 2AC should be dismissed with prejudice.

Dated: July 30, 2018

Respectfully submitted,

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LOCAL RULE 7.1(F) CERTIFICATION

I certify that this case has been assigned to the “litigation track” pursuant to CMO One and that this Memorandum adheres to the page limitations set forth in CMO One § 6(f), CMO Four at 2-3, and L.R. 7.1(f).

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CERTIFICATE OF SERVICE

I hereby certify that on July 30, 2018, a copy of the foregoing **Reply in Support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiffs' Second Amended Complaint** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ Mark S. Cheffo